UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

CHEMIMAGE CORPORATION

Plaintiff.

No.: 1:24-cv-2646

v.

COMPLAINT

JOHNSON & JOHNSON and ETHICON, INC.

Defendants.

Plaintiff ChemImage Corporation ("<u>ChemImage</u>" or "<u>Plaintiff</u>"), by and through its undersigned counsel, brings this action against Defendants Johnson & Johnson ("<u>J&J</u>") and its wholly owned subsidiary, Ethicon, Inc. ("<u>Ethicon</u>" and collectively, "<u>Defendants</u>") and alleges as follows:

NATURE OF THE ACTION

- 1. This is a case about J&J's decision to retreat from its failed play in surgical robotics, breaking the promises it made to ChemImage to develop its life-saving imaging technology. J&J's decision ultimately killed this family-founded company and its technology that could have vastly improved surgical outcomes for millions of people.
- 2. In 2019, J&J and its wholly-owned subsidiary, Ethicon, set out to strengthen its surgical robotics program. Competitors were making strides in this cutting-edge space, and J&J was desperate to catch up. That year, J&J set its sights on Auris Health—acquiring it for \$3.4 billion.
- 3. Then, J&J pursued ChemImage, a company pioneering AI-based light imaging technology. ChemImage's technology would allow surgeons to identify tumors, critical structures, and distinguish between a patient's healthy and diseased tissue, in real-time. This enhanced imaging technology had the potential to revolutionize the medical industry and vastly improve

surgical outcomes. This technology could also enhance the patient experience. With real-time images, patients would no longer have to await biopsy reports, a process that can add as much as an hour to an operating procedure.

- 4. ChemImage's technology offered J&J an advantage over its competitors in the surgical robotics space as they raced to catch up to their competitors. J&J excitedly told ChemImage that it had been searching for this type of technology for a decade. ChemImage was also looking to partner with a much larger medical device company, like J&J, to help bring its cutting-edge technology to market.
- 5. In late 2019, Ethicon, at the direction of J&J, entered into an agreement with ChemImage to jointly develop ChemImage's technology (the "Agreement"). Ex. 1, December 27, 2019 Agreement. Under the Agreement, Ethicon paid ChemImage upfront, with anticipated milestone payments as the project progressed. Ethicon also agreed to pay ChemImage royalties once the technology was commercialized. These royalties were estimated to exceed \$1.5 billion.
- 6. In the first year of the project—despite the disruption of the global COVID-19 pandemic—ChemImage achieved remarkable success, meeting its first milestone.
- 7. Then, J&J's corporate priorities shifted. J&J's play to catch up in the surgical robotics space had failed, for reasons having nothing to do with ChemImage, and J&J tried to silently retreat from its earlier acquisitions. J&J underfunded Auris and eventually instructed Ethicon to abandon ChemImage for purely business reasons. In fact, three days after Ethicon sent its March 2023 termination letter to ChemImage, J&J announced it was laying off 350 employees from its robotics program. ChemImage was another casualty of J&J's cut-throat business decision.
- 8. Under the Agreement, Ethicon could have walked away from the partnership, but if and only if it paid ChemImage a termination fee. This fee would have funded ChemImage's continued operations long enough to find another partner. But rather than honor its

contractual obligations to ChemImage, Ethicon and J&J were determined to terminate the Agreement without paying the termination fee.

- 9. In March 2023, Ethicon, at J&J's direction, sent ChemImage a termination notice for the Agreement, falsely claiming that ChemImage had failed to meet a development milestone.
- Milestone—even if true—violated the Agreement because there were *no* prescribed deadlines to achieve milestones. Further, the Agreement *required* a specific committee (the Joint Steering Committee or "JSC") to determine whether a milestone had been met. Tellingly, Ethicon did *not* obtain a determination from the JSC to support its termination—in fact, Defendants refused to even attend a JSC meeting to discuss the matter. The Agreement also prescribed a cure period, which Ethicon refused to honor. Ethicon terminated *before* the end of the cure period, without allowing ChemImage the required opportunity to cure any purported deficiency.
- 11. J&J and Ethicon never paid ChemImage the required termination fee, despite walking away from their partnership without cause. In doing so, J&J and Ethicon forced ChemImage to close its doors. ChemImage was directly damaged by at least \$1.5 billion in lost milestone and royalty payments. Worse still, ChemImage was forced to lay off 75 employees and halt development of its life-saving technology.

A. The Plaintiff

12. ChemImage is a Pennsylvania corporation with its principal place of business at 7325 Penn Avenue, Suite 200, Pittsburgh, PA 15208.

B. The Defendants

1. J&J

- 13. J&J is a New Jersey Corporation with its principal place of business at One Johnson& Johnson Plaza, New Brunswick, NJ 08933.
 - 14. J&J conducts business throughout the United States, including in New York.
- 15. Since 2022, J&J's medical devices and technology business segment has been referred to as MedTech.

2. Ethicon

- 16. Ethicon is a New Jersey corporation with its principal place of business at U.S. Highway 22 West, Somerville, NJ 08876.
- 17. Ethicon is a wholly-owned operating subsidiary of J&J within the MedTech business segment. Ethicon is responsible for the development and commercialization of J&J's surgical intervention technologies.

JURISDICTION AND VENUE

- 18. This Court has subject matter jurisdiction over Plaintiff's claims pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and the action is between citizens of different states.
- 19. This Court has personal jurisdiction over Ethicon. Pursuant to the Agreement, any dispute arising from the Agreement "shall be submitted [] for resolution by a judge sitting without a jury in the United States District Court for the Southern District of New York, if that court has subject matter jurisdiction[.]" Agreement, App. C at 21.
- 20. This Court has personal jurisdiction over J&J. Specifically, Appendix C to the Agreement provides that any "Disputes that may involve *Affiliates* of [Ethicon or ChemImage], shall be resolved in accordance with [Appendix C to the Agreement]." Agreement, App. C at 20 (emphasis added).
- 21. Pursuant to the Agreement, J&J is an "Affiliate" of Ethicon because it has the "power to direct or cause the direction of the management and policies of [Ethicon]" and because J&J "owns . . . more than fifty percent (50%) of [Ethicon's] voting stock." Agreement § 1. Accordingly, J&J is bound by the Agreement's jurisdiction and venue provisions.
- 22. Further, due to the close relationship between J&J and Ethicon, and J&J's involvement in negotiating and approving the Agreement, it was foreseeable to J&J that it would be bound by the Agreement's jurisdiction and venue provisions.
- 23. Pursuant to 28 U.S.C. § 1391(b), this Court is the proper venue for this action. The Agreement provides that any dispute arising thereunder "shall be submitted [] for resolution by a

judge sitting without a jury in the United States District Court for the Southern District of New York, if that court has subject matter jurisdiction[.]" Agreement, App. C at 21.

CASE SCHEDULE

- 24. The Agreement provides that any disputes that arise between Ethicon, ChemImage, and their Affiliates (*i.e.*, J&J) "shall be resolved in accordance with [Appendix C to the Agreement]." Agreement, App. C at 20.
- 25. Appendix C, titled "Expedited Litigation," includes agreed-upon provisions in the event Ethicon or ChemImage "desires to pursue resolution of the Dispute" in Court. *Id.* at 21.
- 26. The Agreement expressly requires Ethicon, ChemImage, and J&J to "make all filings required by the court on a schedule that will assure trial ready status *eight months after the service of the first complaint* and further agree to make all motions, including motions for summary judgment, on a schedule that will allow them to be fully considered by the court *less than eight months after the service of the first complaint*." *Id.* (emphasis added).

CHOICE OF LAW

27. New York law controls this action. The Agreement provides that disputes arising thereunder "shall be governed by and construed in accordance with the internal laws of the State of New York without reference to conflict of laws principles." Agreement § 12.1.

FACTUAL ALLEGATIONS

I. In 2019, J&J Pursues ChemImage To Advance Its Surgical Robotics Program

- 28. J&J and its subsidiaries operate as a global company engaged in the research, development, manufacture, and sale of a range of healthcare products. J&J's operations are organized into different business segments, one of which is medical devices and technology or "MedTech." Ethicon is one of J&J's wholly-owned subsidiaries in the MedTech space.
- 29. Being at the cutting edge of medical technology is critical to J&J. For J&J and its competitors, surgical robotics is particularly important because it provides access into hospitals

and medical facilities. This materially enhances a company like J&J's ability to sell its core medical products, including sutures and bandages.

- 30. In 2015, J&J entered into a joint venture with Verb Surgical, Inc. ("<u>Verb</u>") to develop a large-scale general surgery robot.
- 31. By 2019, however, J&J was still behind its competitors in the surgical robotics space. That year, revenues in J&J's Advanced Surgery division dropped from single digit to negative growth. Determined to close the gap, J&J began to invest more aggressively in surgical robotics.
- 32. In February 2019, J&J acquired Auris Health, Inc. ("Auris"), a medical robotics company, for \$3.4 billion, with additional potential contingent payments of \$2.35 billion. Later that year, J&J acquired the remaining majority stake in Verb. With both acquisitions, J&J announced that it had "accelerated [its] entry into digital surgery" and was "kicking off a strong cadence of launches that will take place over the next several years."
- 33. By that same time, ChemImage, a Pittsburgh-based company founded in 2002 and operated by leading scientists and doctors, had developed and patented a breakthrough imaging technology. These images could assist with the detection of tumor lesions and margins, key anatomic structures, and tissue perfusion during surgical procedures. ChemImage's cutting-edge technology ran on proprietary, artificial intelligence software that it spent over 15 years developing. ChemImage's software leveraged molecular spectroscopy, digital imaging, and machine learning to achieve real-time detection of biological materials. Once fully developed, ChemImage's technology could create night-vision type capabilities for surgeons, enhancing their view of the surgical field in real time. By incorporating years of medical training and apprentice-based learning into a light-based signal, surgeons would have a simpler way to identify critical structures and abnormal areas during surgery. This technology would revolutionize healthcare.

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¹ "Johnson & Johnson Announces Agreement to Acquire Remaining Stake in Verb Surgical Inc.," J&J Press Release (Dec. 20, 2019), available at https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-agreement-to-acquire-remaining-stake-in-verb-surgical-inc.

34. In furtherance of J&J's corporate strategy to enhance its surgical robotics division, J&J and Ethicon sought to partner with ChemImage and gain access to its groundbreaking technology in 2019. Pitch materials sent to ChemImage by J&J and Ethicon touted how ChemImage would fit into and support J&J's plan to advance its surgical robotics division, along with Auris and Verb.

II. ChemImage, Ethicon, and J&J Negotiate The Agreement

- 35. ChemImage, Ethicon, and J&J negotiated the Agreement, which would govern the development and commercialization of the ChemImage technology (the "Project").
- 36. J&J's then-Vice President, Business Development, Noam Krantz, was one of the primary points of contact listed in its 2019 Letter of Interest to ChemImage. Likewise, Paul Ritchie (J&J's then-Director, Technology Assessment) and Peter Shen (J&J's then-Chief Technology Officer) helped drive these negotiations on behalf of J&J.
- 37. Other senior J&J executives were also involved in overseeing negotiation and approval of the Agreement. For example, ChemImage directly presented its technology to Ashley McEvoy, J&J's then-Worldwide Executive Vice President, MedTech division. Upon information and belief, ChemImage's technology and business plan were then presented in a closed session to Alex Gorsky, J&J's then-Chief Executive Officer and Chairman.
- 38. During the negotiations, Ethicon and ChemImage retained external valuation experts to develop a model for projecting anticipated royalty revenues from the commercialization of ChemImage's technology. The model prepared by Trinity Consultants projected the Project to generate between \$1.3 billion to \$1.7 billion in royalties to ChemImage. ChemImage's decision to move forward with the J&J partnership was based on these projections, which set its expectations for the Agreement.
- 39. Since Ethicon is J&J's wholly-owned subsidiary, J&J had ultimate decision-making authority over Ethicon and approved the Agreement.

- 40. J&J not only approved the agreement on behalf of Ethicon, it also intended to bind itself in the partnership with ChemImage. Indeed, J&J would directly benefit from the Agreement by enhancing its position in the surgical robotics space, which was a priority for J&J in 2019.
- 41. To that end, J&J sought to immediately capitalize on the announcement of its partnership with ChemImage. The press release attached to the Agreement included the headline, "ChemImage Partners *with Johnson and Johnson* to Progress the Development of ChemImage Advanced Visualization Tools in Surgery." Agreement, Ex. E (emphasis added).
- 42. Similarly, on October 14, 2020, J&J's Head of Innovation, Michal Preminger, publicly stated that J&J was "very excited about [the] collaboration" with ChemImage and explained that J&J had "facilitated the collaboration with [its] Ethicon surgery business to develop the company's visualization and awareness of things, AOT platform for healthcare applications."²
- 43. J&J's intended involvement in the partnership was also directly reflected in the Agreement's Notice provision, which required that "[a]ll communications between the Parties with respect to any of the provisions of this Agreement" be sent by ChemImage to J&J's legal department. Agreement § 12.12 (emphasis added).

III. The December 27, 2019 Agreement

- 44. On December 27, 2019, ChemImage and Ethicon, at J&J's direction, entered into the Agreement.
- 45. The Agreement outlined the parameters of the Project, detailed the parties' relative rights with respect to intellectual property, and set forth the allocation of proceeds from any successful commercialization of the technology.

A. The Agreement Provides For In Milestone Payments

46. The Agreement reflects the parties' mutual understanding that the Project's Development Timeline and parameters would evolve over time. The Agreement was designed to

² "J&J Innovation - Michal Preminger and Stephen Pitt," Agile Giants Podcast (Oct. 14, 2020), available at https://agilegiants.seanammirati.com/jj-healthcare-innovation.

accommodate an iterative development process and required the parties to address Project parameters collaboratively.

- 47. The parties agreed to mark their progress through six development milestones and six regulatory milestones (the "Milestones"). See Agreement, Ex. B. However, the Agreement prescribed no fixed deadline by which ChemImage was required to achieve any of the Milestones. Id. Instead, the Agreement set out a range of "target dates" for certain research and development tasks associated with the Project and "anticipated invoice date[s]" to be paid by Ethicon for "Major R&D tasks;" it did not include specific dates by which any Milestone had to be met. Agreement, Ex. B at 2-3.
- 48. Likewise, the Agreement did not mandate the technical requirements or data protocols required to meet each Milestone.

B. Section 2.4: The Agreement Requires The Joint Steering Committee To Determine Whether A Milestone Had Been Met

- 49. The Agreement required that the parties work together to develop assessment protocols and success parameters for the Project. This was to be accomplished through the formation of the Joint Steering Committee ("<u>JSC</u>").
- 50. Pursuant to Section 2.4.1 of the Agreement, the JSC was to consist of "two [ChemImage] members and two [Ethicon] members, each of whom shall be senior employees authorized to make the decisions *for its respective Party* allocated to the JSC." Agreement § 2.4.1 (emphasis added). At all times, the JSC was to include two senior employees each from ChemImage and Ethicon with decision-making authority. *Id*.
- 51. Francesc Fernandez, Vice President of Research & Development (Capital and Advanced Imaging) was one of Ethicon's key decision-making members on the JSC.
- 52. Notably, J&J also operated as a "Party" to the Agreement under Section 2.4.1 by appointing several members to the JSC. At different times, J&J's JSC members or meeting attendees included Paul Ritchie (J&J's then-Director, Technology Assessment), Sarah Moore (J&J's then-Business Unit Lead, Advanced Imaging), Tamara Lanier (J&J's then-Global

Marketing Innovation & Pipeline Leader, Digital Surgery and Robotics), and Marco Kristensen (J&J's Senior Engineering Manager and Technical Lead).

- 53. The JSC was required to meet at least once every six months, with a minimum of one ChemImage and one Ethicon/J&J member required for a quorum. Agreement § 2.4.2.
- 54. The JSC was responsible for making decisions around key processes and deliverables that would move the Project forward, including: (1) adjusting the Development Plan and Timelines, (2) adjusting parameters for the Milestones, (3) determining whether Milestones had been met, (4) making recommendations for any potential budget adjustments, (5) making recommendations to the plan for developing the proposed technology, and (6) providing marketing advice to Ethicon. *Id.* § 2.4.1.
- 55. All of the JSC's decisions, including the critical task of determining whether ChemImage achieved a Milestone, required the JSC's unanimous vote, with Ethicon/J&J and ChemImage each receiving one vote. *Id.* § 2.4.3. In the event the JSC was unable to reach a unanimous decision, the Agreement outlined an alternative dispute resolution process. *Id.*

C. Section 5: Defendants Determine That ChemImage's Technology Is Highly Valuable

- 56. Based on ChemImage's pioneering technology, Ethicon agreed to pay ChemImage an upfront payment of Agreement § 5.2.
- 57. Ethicon also agreed to pay ChemImage in Development and Regulatory Milestones. *Id.* § 5.3; *id.*, Ex. B at 2-3.
- 58. The Agreement also contemplated royalty payments to ChemImage upon commercialization. *Id.* § 5.4. At the outset of the partnership, the parties projected the potential royalty payments to be valued at approximately \$1.5 billion to ChemImage.

D. Section 10 Provides For Two Unambiguous Termination Provisions

59. Section 10 of the Agreement sets forth two unambiguous and fiercely negotiated termination provisions. The Agreement permits Ethicon to terminate the Agreement either (a) for

cause or (b) without cause, triggering a termination fee. Ethicon's pretextual termination attempts to evade the plain language of these obligations.

1. Termination For Cause

- 60. Under Section 10.3.1, Ethicon was permitted to terminate the Agreement "for Cause" if ChemImage "materially breached or defaulted in the performance of any of its obligations" under the Agreement and if the breach "continued for thirty (30) days" after receiving Ethicon's written notice. Agreement § 10.3.1.
- 61. The Agreement contains only *one* definition of a material breach by ChemImage. Specifically, ChemImage would materially breach the Agreement if it "fail[ed] . . . to achieve a Development Milestone as described in Exhibit B." *Id.* § 10.3.2.
- 62. Critically, the Agreement requires that the *JSC* "determine whether the Milestones . . . have been met." *Id.* § 2.4.1(b). Neither Ethicon nor J&J can make this determination unilaterally. *Id.*
- 63. In the event Ethicon terminated the Agreement for cause, it was required to provide ChemImage with a written notice that "specifies in reasonable detail the nature of the breach or default, [and] states that [ChemImage] is required to cure such breach or default and states that failure to cure such breach or default will result in termination of this Agreement." Id. § 10.3.1 (emphasis added).
- 64. The Agreement permitted ChemImage at least 30 days to cure a material breach and stated that "if the breach or default is not reasonably capable of being cured within such 30-day period, termination shall not be effective" so long as ChemImage "commences cure of the breach or default within such 30-day period and thereafter diligently prosecutes such cure to completion." *Id.*
- 65. If Ethicon terminated for cause, "all licenses and sublicenses . . . shall automatically terminate and such licenses revert to the owner of the applicable Intellectual Property," and ChemImage would grant Ethicon limited intellectual property rights. Agreement § 10.3.3 ("[ChemImage] hereby grants to [Ethicon] an exclusive, assignable (consistent with Section 12.8)

and sublicensable license to the [ChemImage] Core IP, and a non-exclusive, assignable (consistent with Section 12.8) and sublicensable license to the [ChemImage] Developed Lightsphere[.]").

66. The Agreement imposed no termination fee in the event of proper termination "for Cause" under Section 10.3.

2. Termination Without Cause Requires A Termination Fee

- 67. Ethicon was also permitted to terminate the Agreement "without Cause." Agreement § 10.4.
- 68. However, Ethicon's termination without cause was "effective *only if*, within one hundred twenty (120) days of its provision of written notice," Ethicon paid ChemImage "a non-refundable sum equal to _______." *Id.* § 10.4.1(a) (emphasis added).
- 69. If Ethicon terminated without cause under Section 10.4, Ethicon would relinquish all rights to ChemImage's Intellectual Property, and Ethicon would grant ChemImage a non-exclusive license to any jointly developed intellectual property so it could continue to develop its life-saving technology. Agreement § 10.4.4 ("[Ethicon] grants to [ChemImage] a royalty-free, non-exclusive license, with the right to grant sublicenses, to the Collaboration IP and [ChemImage] Developed EndoVere IP in the Territory.").
- as protection in the event of a termination without cause. Because ChemImage was required to redirect resources to fulfill its new obligations to Ethicon and J&J under the Agreement, this fee would provide ChemImage necessary protection and funds if J&J decided to pull the plug on this bet-the-company partnership.

IV. ChemImage Makes Progress Under The Agreement And Achieves Milestone 1A Despite Ethicon's Delays

71. Less than a year into the Project, ChemImage achieved remarkable success. In October 2020, the JSC determined that ChemImage achieved Milestone 1A.

- 72. ChemImage was able to achieve Milestone 1A notwithstanding delays caused by the COVID-19 pandemic which, among other things, forced the shutdown of the J&J testing facility at Blue Ash, where J&J insisted all Project research be done.
- 73. Tellingly, the activities necessary to achieve Milestone 1A were largely within ChemImage's control. In contrast, the activities necessary to achieve later Milestones were dependent on Ethicon and J&J providing the necessary hardware to pair ChemImage's technology with an appropriate device.
- 74. Future development efforts were delayed by Defendants' failure to timely provide the necessary equipment, facilities, testing support, and materials to continue development.
- 75. Ethicon also unilaterally pushed for extensions of the relevant deadlines. In early May 2021, Ethicon proposed revising the Agreement to extend the date by which Ethicon was obligated to make its first commercial sale (the "Launch Deadline") by *eighteen months*.
- 76. Around the same time, J&J's robotics program was struggling, including facing major developmental delays with its acquired technology from Auris and Verb. Upon information and belief, these issues were due, at least in part, to J&J's failure to properly fund the development of its surgical robotics program following a flood of expensive acquisitions. In the second half of 2020, Ashley McEvoy, J&J's then-Worldwide Executive Vice President, MedTech division, was informed that J&J was underspending on the research and development funding necessary to make its robotics surgery ventures successful.³ J&J's former Senior Financial Director, Jill McManus, even stated, "When will JNJ learn that our acquisitions fail *because we never properly fund them*?"

³ See Fortis Advisors LLC, solely in its capacity as representative of former stockholders of Auris Health Inc. v. Johnson & Johnson, et al., C.A. No. 2020-0881-LWW (hereinafter, "Fortis Advisors v. Johnson & Johnson"), Plaintiff Fortis Advisors' Timeline of Key Events (filed Feb. 23, 2024) at 44.

⁴ Fortis Advisors v. Johnson & Johnson, Plaintiff Fortis Advisors' Timeline of Key Events at 42 (emphasis added).

- 77. After its fumbled surgical robotics play, J&J changed its corporate strategy and quietly tried to retreat from its partnership with ChemImage. ChemImage struggled to get engagement and cooperation from Ethicon's and J&J's JSC members. There was frequent turnover of Ethicon's and J&J's designated members of the JSC, and new appointees were unfamiliar with the technology. Ethicon and J&J's JSC members also deliberately avoided discussing the technical details of the Project.
- 78. In a deliberate effort to thwart progress, Ethicon and J&J also pressured ChemImage to remove its most technically knowledgeable member—ChemImage founder, Dr. Patrick Treado—from the JSC, arguing that he presented *too detailed* information. Tellingly, the details Defendants took pains to *avoid* discussing at the JSC would later form the basis of their pretextual termination of the Agreement.
 - 79. Despite these issues, ChemImage forged ahead.
- 80. When the JSC was able to convene (at ChemImage's insistence), it discussed the Development Plan and modified the timeline to reflect the then-current state of the Project. Early JSC meeting minutes reflect the parties' expectation that "[d]eadlines are considered to be targets."
- 81. Once the Project had progressed enough to require decisions involving study design, research methodology, and data analysis and integrity, ChemImage and Ethicon formed the Data Review Board (or "DRB").
- 82. The DRB was established to "[i]mprove the data catalog used for deep learning training, testing, and validation through systematic review of questionable data and processing strategies" and was responsible for reviewing data quality, data processing strategies, and assessment methods. The DRB included eight Ethicon/J&J members and eleven ChemImage members, with five voting members allocated to each party.
- 83. Employees from both Ethicon and J&J participated in DRB meetings. Murat Aksoy, an employee of J&J MedTech, was one of Ethicon's five voting members on the DRB.

- 84. J&J also retained a third-party consultant, Cambridge Consultants, to assist with its evaluation of the algorithm and data framework. Cambridge Consultants actively participated in DRB meetings.
- 85. The DRB agreed that it would endeavor to reach consensus on all decisions, including on the "inclusion or exclusion" of data.
- 86. The DRB recognized that, due to the machine learning on which ChemImage's technology is predicated, the inclusion of imperfect information in data sets used to train the algorithm could result in mislabeling critical structures in future scans. Accordingly, one technical issue decided by the DRB was whether and how to ensure that only confirmed accurate data was included in validation sets.
- 87. To avoid errors caused by training ChemImage's technology with inaccurate data, the DRB determined that "ignore labels" should be applied to any object in a data set that was not affirmatively identified with certainty by a trained human so that the image would be excluded from the calculations for evaluation. The DRB's approved process embodied the maxim, "good data in, good data out"—which is essential to machine learning.
- 88. The DRB further determined that the agreed protocol for applying ignore labels did not require further review. ChemImage implemented the DRB's ignore-label process.

V. ChemImage Achieves Milestone 1B

- 89. Achieving Milestone 1B required ChemImage software to be paired with Ethicon-designed hardware. Agreement, Ex. B. In mid-2022, the JSC convened and, at Ethicon's encouragement, narrowed the scope of Milestone 1B to focus only on veins, arteries, and bile ducts ("VAB"), postponing work on ureters and nerves.
- 90. With the narrowed VAB scope in place, ChemImage prepared an interim report on its progress toward Milestone 1B for the JSC's review at the October 14, 2022 JSC meeting. Following this review, the JSC finalized the Acceptance Protocol for Milestone 1B.

- 91. At that meeting, Ethicon noted that ChemImage had met its Q3 goals and that "Q3 Interim results are marked as good performance[.]" The JSC noted no upcoming urgent business or red flags that would indicate the partnership was at risk.
- 92. After multiple collaborative rounds of testing and review, and in compliance with the JSC-mandated Acceptance Protocol, ChemImage submitted the Milestone 1B Final Report on December 16, 2022 (the "Final Report"). The Final Report incorporated the DRB's specified use of ignore labels and demonstrated that the criteria for Milestone 1B had been achieved. The Final Report demonstrated "[s]uccessful in-vivo demonstration with a prototype . . ." in VAB, consistent with the parameters outlined in the Agreement and as agreed-upon by the JSC. *See* Agreement, Ex. B.
- 93. ChemImage was not required to submit the Milestone 1B Final Report on December 16, *or on any other date*, since the Agreement did not prescribe *any* deadlines for the Milestones. *See* Agreement, Ex. B.
- 94. Still, ChemImage submitted the report and awaited the JSC's determination. Despite the fact that the Agreement expressly requires that the JSC "determine whether the Milestones ... have been met" (Agreement, § 2.4.1), the JSC *never* determined whether Milestone 1B had been achieved.
- 95. For months, ChemImage insisted that the JSC make its required determination but Ethicon and J&J refused. In fact, Ethicon and J&J refused even to attend further JSC meetings, without any explanation.

VI. Ethicon And J&J Terminate the Agreement Without Cause

96. On March 6, 2023, Ethicon sent ChemImage a one-page letter advising of Ethicon's intention to terminate the Agreement "for cause for failure to achieve a Development Milestone, which constitutes a Material Breach" (the "Termination Letter"). Ethicon claimed that the Final Report for Milestone 1B was "not evaluable" and did not address Ethicon's concerns regarding data collection, ignore labels, and processing practices.

- 97. The Termination Letter also cited to Ethicon's purported statement in June 2022 that the Project was at risk of termination if ChemImage did not demonstrate technical feasibility by year-end. However, the Agreement did not require technical feasibility by December 2022, and this deadline was never established by the JSC.
- 98. Rather than provide ChemImage with the "reasonable detail" necessary to cure any alleged breach, as required by the Agreement, Ethicon simply stated that it was "terminating [the Agreement] effective thirty (30) days from the date [of the Termination Letter]."
- 99. ChemImage responded to the Termination Letter stating that it was prepared to cure any identified deficiency or purported breach consistent with the Agreement but that, given the nature of the Project and lack of reasonable detail in the Termination Letter, it could not proceed to cure without additional information and cooperation from Ethicon. Ethicon refused to cooperate or provide the requested information.
- 100. ChemImage then informed Ethicon that it was commencing the dispute resolution process, which suspends the running of the cure period "until the date such proceeding has been concluded." Agreement § 10.3.1. As required by the Agreement, ChemImage also requested an in-person meeting of senior executives within 10 days. Agreement § 12.2.
- 101. On April 7, 2023, Ethicon and ChemImage met in-person but made no progress toward resolving the dispute. Ethicon simply reiterated its unilateral determination that there had been an incurable material breach and asserted that the Agreement would terminate on April 26, 2023.
- 102. On April 17, 2023, ChemImage provided Ethicon with a Notice of Mediation in accordance with the dispute resolution procedure in the Agreement. Agreement, App. C at 1.
- 103. Ethicon then unilaterally terminated the Agreement effective April 26, 2023, *before the cure period ended.*
- 104. Ethicon's purported termination of the Agreement was nothing more than a pretextual attempt to avoid its contractual obligations, including payment of Milestone 1B and the termination fee.

- 105. Upon information and belief, Ethicon's pretextual termination was done at J&J's direction. At some point prior to termination, J&J made the strategic decision to retreat from aspects of its failed surgical robotics play, notwithstanding contractual obligations to ChemImage. Defendants' pretextual termination would also preclude ChemImage from partnering with a competitor to develop and commercialize its technology (where J&J had previously failed) by purporting to tie up ChemImage's intellectual property pursuant to Section 10.3.3 of the Agreement.
- 106. Notably, on March 9, 2023, *three days* after Ethicon sent ChemImage the Termination Letter, J&J announced it was laying off 350 people in its robotics unit.⁵
- 107. This shift in J&J's corporate priorities has resulted in years of litigation related to its acquisition of Auris. In that litigation, filed in the Delaware Court of Chancery, former Auris stockholders have alleged that J&J, Ethicon, and various J&J executives defrauded former Auris shareholders out of millions of dollars in developmental and commercial milestones. *See Fortis Advisors v. Johnson & Johnson*, C.A. No. 2020-0881-LWW (complaint filed Oct. 12, 2020). They also allege that defendants failed to use commercially reasonable efforts to develop Auris' robotics surgery technology. *Id.* J&J and Ethicon's Agreement with ChemImage was a casualty of the same shift in J&J's corporate priorities.

VII. ChemImage Has Suffered Significant Harm As A Result of Defendants' Breaches

108. Like the other termination provisions, the termination fee for a "without Cause" termination under Section 10.4.2(a) was fiercely negotiated, in part, to ensure that ChemImage would have funding to continue its operations and find another partner if Defendants reneged on the Agreement. By purporting to terminate for cause and withholding the payment, Defendants caused ChemImage to suffer damages far in excess of

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Nick Paul Taylor, *J&J lays off 350 people at robotics units, says 'we have to get better' with Ottava*, MedTech Dive (published Mar. 9, 2023, updated Mar. 10, 2023), *available at* https://www.medtechdive.com/news/jnj-layoffs-auris-california-robotic/644544/#:~:text=Since%20then%2C%20the%20company%20has,anticipated%20launch%20by%20two%20years.

- 109. Without the funding and unimpeded rights to its intellectual property, ChemImage was frozen, losing the full value of its technology, as well as all Milestone and Royalty Payments payable under the Agreement. These direct damages are in excess of \$1.5 billion.
- 110. As a result of Defendants' pretextual breach, ChemImage initially furloughed virtually all of its employees, optimistic that it might reach a resolution. Once it was clear J&J had long-ago decided to terminate the Project, ChemImage was forced to lay off all of its employees and eventually close its doors. As a result of Ethicon and J&J's actions, 75 people lost their jobs, and ChemImage could no longer pursue development of its life-saving technology.

COUNT I

Breach of Contract (Against Ethicon and J&J)

- 111. Plaintiff incorporates and realleges each and every allegation above as if fully set forth herein.
- 112. Plaintiff and Ethicon are parties to the Agreement, which is a valid and binding contract.
- Agreement was negotiated by, presented to, and approved by senior J&J employees; (2) J&J contracted for express notice rights in the Agreement, securing its continued participation in the Agreement under Section 12.12; (3) J&J is expressly defined as an "Affiliate" of Ethicon under the "Expedited Litigation" provision in Appendix C to the Agreement; (4) J&J participated *as a Party* to the Agreement under Section 2.4.1, by appointing members to the JSC; and (5) senior J&J employees participated in the JSC and DRB.
- 114. As evidenced by J&J's public statements on its strategic partnership with ChemImage, J&J directly benefited from the Agreement by enhancing its position in the surgical robotics space. This was a business priority for J&J in 2019.

- 115. ChemImage performed its obligations under the Agreement, including by working to advance the Project (in spite of Defendants' delays) and by adhering to the dispute resolution procedures outlined in the Agreement (even when Defendants did not).
 - 116. Defendants breached the Agreement in no fewer than four, independent ways.
- 117. First, Defendants breached the Agreement when they terminated "without Cause" and without paying the termination fee. Defendants' pretextual justification of ChemImage's purported failure to meet Milestone 1B—even if true—fails because there was **no** deadline to meet **any** Milestone. See Agreement, Ex. B.
- 118. Second, Defendants breached the Agreement when they purported to unilaterally terminate the Agreement for cause, even though the JSC had not determined whether Milestone 1B had been met. The Agreement expressly requires that the JSC (not Ethicon or J&J) make that critical determination. *Id.* § 2.4.1(b).
- 119. Third, Defendants breached the Agreement when they terminated before the cure period ended. *Id.* § 10.3.1.
- 120. Fourth, Defendants' pretextual Termination Letter also breached the Agreement by failing to "specif[y] in reasonable detail the nature of the breach or default," thus denying ChemImage the opportunity to cure any alleged deficiencies. *Id.* § 10.3.1.
- 121. As a result of Defendants' breaches, ChemImage suffered direct damages, including but not limited to at least \$1.5 billion in lost Development Milestone Payments, Regulatory Milestone Payments, and Patent Royalties. *Id.* at Ex. B.
- 122. The Agreement expressly provides "that liability for lost Development Payments, Milestone Payments or Patent Royalties payable hereunder shall not be deemed anything other than direct damages." *Id.* § 8.4.

COUNT II

Tortious Interference With Contract (Against J&J)

123. Plaintiff incorporates and realleges each and every allegation above as if fully set

forth herein.

- 124. Plaintiff and Ethicon are signatories to the Agreement, which is a valid and binding contract.
- 125. J&J had knowledge of the Agreement. Ethicon is a wholly-owned subsidiary of J&J. The Agreement was negotiated, presented to, and approved by J&J executives. At all times during the Agreement's operation, J&J was aware of the Agreement and the obligations imposed on Ethicon.
- 126. Upon information and belief, due to J&J's shifting corporate priorities in the surgical robotics space, J&J knowingly and maliciously caused Ethicon to terminate the Agreement "for Cause" when both J&J and Ethicon knew that no cause existed. Specifically, the Agreement did *not* prescribe any deadlines for Milestones and the JSC had *not* made any determination on Milestone 1B.
 - 127. J&J knowingly caused and directed Ethicon to breach the Agreement anyway.
- 128. But for J&J's directive, Ethicon would not have purported to terminate the Agreement "for Cause." Rather, J&J's corporate strategy drove this decision after its lackluster performance in the surgical robotics space.
- 129. As a result of J&J's tortious interference with the Agreement, ChemImage suffered damages, including but not limited to at least \$1.5 billion in lost Development Milestone Payments, Regulatory Milestone Payments, and Patent Royalties. *Id.* at Ex. B.
 - 130. J&J is jointly and severally liable for these damages.

COUNT IV

Declaratory Judgment (Against Ethicon)

- 131. Plaintiff incorporates and realleges each and every allegation set forth above as if fully set forth herein.
- 132. The Agreement provides that, in the case of termination without cause, "all licenses and sublicenses granted under Sections 4.1 and 4.2 shall automatically terminate and such license

rights shall revert to the owner of the applicable Intellectual Property." Agreement, § 10.4.4.(a).

133. Because Ethicon effectively terminated the Agreement without cause, ChemImage is entitled to a declaration clearing all patents and other intellectual property developed pursuant to the Agreement for unfettered use and development by ChemImage.

COUNT V Attorneys' Fees and Expenses (Against Ethicon and J&J)

- 134. Plaintiff incorporates and realleges each and every allegation set forth above as if fully set forth herein.
- 135. The Agreement provides that "the prevailing Party in any action commenced under this [Agreement] shall be entitled to receive reasonable attorneys' fees and court costs as determined by the court hearing the Dispute." Agreement, App. C.
- 136. ChemImage is entitled to reimbursement of attorneys' fees and expenses if it recovers any quantum of damages prayed for.

PRAYER FOR RELIEF

- 137. WHEREFORE, Plaintiff prays for relief and demands judgment against Defendants, jointly and severally, as follows:
 - A. A joint-and-severable award of damages from Defendants, including but not limited to:
 - i. in lost Development Milestone Payments;
 - ii. in lost Regulatory Milestone Payments; and
 - iii. \$1.5 billion in lost Patent Royalties;
 - B. Declaratory relief clearing all patents and other intellectual property developed pursuant to the Agreement for unfettered use and development by ChemImage;

- C. An award of Plaintiff's attorneys' fees, costs, expenses, and disbursements in this action;
- D. Pre-judgment and post-judgment interest;
- E. For the Court to enter a case schedule consistent with the "Expedited Litigation" provisions in Appendix C to the Agreement, requiring the parties to be trial ready in eight months; and
- F. Such other and further relief as the Court deems just and proper.

DATED: April 4, 2024

QUINN EMANUEL URQUHART & SULLIVAN, LLP

Alex Spiro

Andrew J. Rossman

Courtney C. Whang

51 Madison Avenue, 22nd Floor

New York, New York 10010-1601

Telephone: (212) 849-7000

Fax: (212) 849-7100

alexspiro@quinnemanuel.com

andrewrossman@quinnemanuel.com courtneywhang@quinnemanuel.com

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